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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/810,783	03/16/2001	Raphael C. Wong	BRA4.PAU.02	9163

7590 04/28/2004

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EXAMINER

NGUYEN, BAO THUY L

ART UNIT PAPER NUMBER

1641

DATE MAILED: 04/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/810,783	Applicant(s) WONG, RAPHAEL C.	
	Examiner Bao-Thuy L. Nguyen	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 February 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 10-18 and 23-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10-18 & 23-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

#### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/26/2004 has been entered.
2. Claims 10-18 and 23-29 are pending.

#### *Claim Rejections - 35 USC § 112*

3. Claims 10-18 and 23-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 10 and 23 are vague and indefinite because it is unclear what reagents are present on the drug test strip and the adulterant test strip. For example, what limitations are in the "non-immunoassay adulterant test strip" that allows it to be an adulterant test strip?

#### *Claim Rejections - 35 USC § 102*

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international

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application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

5. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

6. Claims 10-18 and 23-29 are rejected under 35 U.S.C. 102(e) as being anticipated by Lee (US 6,514,769).

Lee discloses a device for detecting analytes in a sample while simultaneously evaluating whether the analyte sample has been adulterated or other wise compromised. The device of Lee comprises one or more analyte test strips and integrity pads separate from the analyte test strip via a fluid barrier. (Column 1, lines 49-63; and column 6, lines 57-59). Each of the analyte test strip is separated from the next within a housing by raised spacer, and the portion of the housing that overlies the test and control zones is transparent to permit viewing of the results. (Column 2, lines 6-17) The fluid barrier between the analyte test strip and the integrity pad includes a physical gap or a hydrophobic film disposed on a carrier membrane. Thus, sample fluid that has not passed through analyte test is brought into contact with integrity determinant pad via passage through the carrier membrane. The carrier membrane is physically separated from analyte test strip by a layer of non-bibulous paper. (Column 6, line 54 through column 7, line 2). Lee teaches that the integrity monitoring system can be made to determine the pH of the test sample, the specific gravity or proteins contents of a sample. (See

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column 8, lines 22-31; and 57-67). Lee also disclose an embodiment where the analyte test strip and the integrity determinant pad occupies separate slots in the base holder (column 2, lines 26-29; and column 9, lines 62-64), or the sample integrity pad can be placed beneath the carrier membrane accompanied by a window to permit viewing of the results (column 9, lines 47-64).

### *Response to Arguments*

7. Applicant's arguments filed 2/4/04 have been fully considered but they are not persuasive.

Applicant argues that claim 10 has been recited to include the limitation that the drug test strip is disposed within a separated component than that of the adulterant test strip, and that unlike Lee, the instant adulterant test strip and the drug test strips are not coupled to any common membrane.

This argument has been fully considered but is not deemed to be persuasive. In addition to an embodiment where the drug test strip and the adulterant test strip both rest on a membrane separated from each other by a physical barrier, Lee also teaches an embodiment where the drug test strip and the adulterant test strip occupy separate slots in a base holder. See column 9, lines 62-64 and column 2, lines 26-29). Specifically, Lee teaches that in such an embodiment, only the adulterant test strip rests on the carrier membrane.

### *Conclusion*

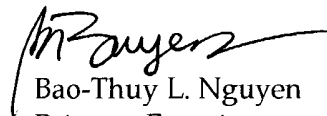
8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday and Thursday from 9:00 a.m. - 4:30 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Bao-Thuy L. Nguyen  
Primary Examiner  
Art Unit 1641